MHRA colleagues in attendance:

[redacted] SCS level

[redacted] SCS level

[redacted] SCS level

[redacted], SCS level

[redacted] SCS level

[redacted] SCS level

[redacted] SCS level

Minutes of the meeting between the US Federal Drug Agency and the MHRA on 16th November 2020

Today MHRA officials from Policy, Licensing, IE&S and NIBSC met with colleagues from FDA's Centre for Biologics Evaluation and Research (CBER), which includes their Office of Vaccines, Division of Viral Products and Office of Compliance and Biologics Quality.

Update on USA Timeline:

- 13/11/2020 à Conversation with Pfizer and requested more detail on CMC package. FDA were promised a comprehensive package. They confirmed they do not currently have enough data on quality to make a decision.
- As early as week commencing 23/11 à it is expected the company may submit an Emergency Use Authorisation (EUA) request with interim data. No specific date was given for when FDA would issue a response but conscious of time pressures.
- 26/11 à information may become available on some GCP inspections that are taking place (FDA happy to share that information when it becomes available)
- To note, that under emergency use authorisation provision, there is not a requirement for formal lot testing (FDA won't do any actual testing on the batches).

Wider meeting notes:

FDA on timelines

Had a discussion with Pfizer last Friday and wanted more detail on CMC package (have been promised a comprehensive package).

FDA feel at present they don't have enough information to make a decision re product quality. FDA need to review CMC package very quickly and anticipate a large number of gaps.

If an EUA request is submitted (note that this is requested by the company, distinction from the UK and Reg 174) which is very likely and may be as early as next week), interim data is sent with this. Once the FDA have this request, they are under pressure to review the CMC package as quickly as possible.

[redacted] requested further information/understanding of the manufacturing issue re [SECTION 43 REDACTION] and future MHRA-CBER engagement is expected on this.

Batch Release

[redacted] (NIBSC) explained about the concerns re batch release and that NIBSC had been promised material due to arrive today.

FDA confirmed under emergency use authorisation provision, there is not a requirement for formal lot testing (FDA wouldn't do any actual testing on the batches). But FDA would want to see their protocols, data, and test results. They have information from the clinical trials material which the company wanted to use as material to demonstrate quality and consistency of the product but don't have this data for scaled up batches and the lot that they produced. It is hoped that some of this will be demonstrated through the comprehensive data package promised.

[redacted] asked for any comment on AstraZeneca correspondence for FDA. FDA did not have this information to hand but would follow up.

Further Regulatory issues

Inspections

FDA confirmed under EUA, they would perform site visits (not full inspections) which are in part to provide guidance to manufacturers in terms of development and any GCP issues. There is also an option to issue a waiver based on inspection history.

FDA noted that there are some GCP inspections that are taking place and is happy to share that information when it becomes available (hopefully within the next week).

There was further discussion about MHRA and FDA concerns on CMC and the little time to do expedited review with lots of data. FDA confirmed importance of transparency and being forthcoming about data gaps and how decisions are being made on risk-benefit.

Meeting was concluded with both regulators agreeing that a small core group should keep in contact on open exchange particularly when issues in getting information about different products. International Office will lead on follow up with CBER International colleagues, to ensure relevant follow up conversations are in place in near future.